

OFFICE OF SPECIAL MASTERS

(No. 93-0264V)

(Filed December 17, 1998)

SETH R. PLATT,

Petitioner,

v.

SECRETARY OF THE DEPARTMENT OF
HEALTH AND HUMAN SERVICES,

Respondent.

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Clifford J. Shoemaker, Vienna, Virginia, for petitioner.

Gabrielle Manganiello, United States Department of Justice, Washington, D.C., for respondent.

DECISION

WRIGHT, Special Master.

On April 30, 1993, petitioner filed a claim under the National Vaccine Injury Compensation Program (hereinafter "Vaccine Act" or the "Act").⁽¹⁾ Petitioner claims that a measles-mumps-rubella ("MMR") vaccination administered to him on June 4, 1990, caused him to suffer acute pancreatitis and thereafter chronic remitting pancreatitis.

I.

PROCEDURAL BACKGROUND

On June 25, 1993, respondent filed a report in this matter recommending compensation be denied since petitioner had not shown that the vaccination in question actually caused Seth's injuries. An evidentiary hearing was held in this matter on June 5, 1995, and continued on December 16, 1996. Petitioner testified and presented the factual testimony of his father, Frank Platt. Also testifying for petitioner were Dr. Mark Geier, Dr. Joseph Bellanti, Dr. Sidney Berezin and Dr. Myron Shoham. Testifying for

respondent were Dr. John Bacon, Dr. Martin Maksimak and Dr. John Sever. Petitioner submitted a post-hearing brief ("P. Brief") on November 14, 1997. Respondent filed a responsive brief ("R. Brief") on December 15, 1997. Petitioner filed a reply to respondent's brief on February 18, 1998. ("P. Reply Brief").

II.

FACTUAL BACKGROUND

The following evidence is contained in the record in this matter:⁽²⁾

Seth Platt was born on June 5, 1974, after an apparently uncomplicated pregnancy and uneventful delivery. P. Ex. 2. Seth was seen frequently by his pediatrician, Dr. Sidney Berezin, during his childhood. His examinations were generally unremarkable. P. Ex. 4. When he was nine years old, Seth's pediatrician noted his obesity. P. Ex. 4 at 8. On January 14 and 15, 1985, Seth was seen by Dr. Berezin for vomiting and slight tenderness in the right lower quadrant. *Id.* Seth received the normal childhood immunizations, apparently without any untoward reactions. P. Ex. 4 at 2, 3; P. Ex. 14.

On June 4, 1990, the day before his 16th birthday, Seth received an MMR booster immunization at the office of Dr. Berezin. P. Ex. 4 at 10; P. Ex. 14. The immunization was administered in the late afternoon. P. Ex. 1 at 1. That evening, Seth felt ill and went to bed early. The next morning, Seth awoke with "intense abdominal pain located precisely in the center of [his] abdomen." *Id.* Seth's father, Mr. Frank Platt, took Seth that day to obtain his driver's permit. Seth was in too much pain to drive home and stayed home from school that day sleeping and drinking gingerale and tea. *Id.* The next morning, Seth continued to feel intense pain in his abdomen and his father took him to Dr. Berezin, who referred Seth to Dr. Stewart Berezin, a pediatric gastroenterologist. P. Ex. 1 at 1-2. Dr. Stewart Berezin diagnosed acute pancreatitis and admitted Seth to the hospital at Westchester County Medical Center, where he remained for fifteen days. P. Ex. 1 at 2.

Since he recovered from his initial bout of pancreatitis, Seth has suffered many recurrent attacks of pancreatitis and has been hospitalized numerous times. *Id.* Because of Seth's recurring bouts of pancreatitis, he underwent an endoscopic retrograde cholangiopancreatography study ("ERCP") in June 1991 to attempt to find any anatomic abnormality as the cause of his pancreatitis. The study revealed that the main pancreatic duct and biliary tree were normal, but the secondary pancreatic ducts showed changes consistent with chronic pancreatitis. P. Ex. 5 at 18. No specific anatomic etiology was found for Seth's chronic pancreatitis. *Id.* Two further ERCP studies, in February 1993 and December 1993, also revealed no specific etiology for Seth's chronic pancreatitis. P. Ex. 17 at 37-38; P. Ex. 25 at 27. Seth still suffers from chronic pancreatitis. Tr. at 23, 34.

Seth testified during the evidentiary proceedings that prior to the administration of the MMR vaccine on June 4, 1990, he had experienced abdominal pain but he "didn't have anything even remotely similar to this. It was in a completely different area of my abdomen. It was lower in . . . my stomach, like a stomach ache. But nothing up in the upper part of my abdomen like pancreatitis."⁽³⁾ Tr. at 8. Although in the past, Seth had had stomach pains not associated with nausea or diarrhea, he testified they weren't "even remotely" like the pain he experienced that day.⁽⁴⁾ Tr. at 9-10.

Mr. Frank Platt, Seth's father, testified generally corroborating his son's testimony. He testified he never gave a history indicating Seth had experienced similar pains to those he suffered after his MMR vaccination. Tr. at 44.

Medical Records

The medical records of Seth's initial hospitalization at Westchester County Medical Center contain several references to earlier episodes of similar abdominal pain. Specifically, an emergency room initial history states, "similar episodes in the past which resolved spontaneously." P. Ex. 18 at 41. Further emergency room progress notes state, "He experienced similar abdominal pain in past few occasions - lasted 4-5 days in duration with spontaneous recovery." P. Ex. 18 at 44. Hospital progress notes indicate, "There is a past [history of] 3-4 such episodes over the past year, each lasting 3-4 days, consisting of dull [abdominal] pain, no vomiting or other associated symptoms. . . ." P. Ex. 18 at 46. Another hospital progress note indicates a prior medical history of "2 episodes of epigastric crampy pain in past 1 year, resolved spontaneously, lasting for 4 days." P. Ex. 18 at 48. The same notes include an "Assessment" of a "16 [year old male] 3rd episode of epigastric pain presently worse than usual with radiation to the back." P. Ex. 18 at 49. At the time of his first episode of pancreatitis, Seth was evaluated by Dr. Howard Bostwick, a pediatric gastroenterologist. By letter dated June 25, 1990, Dr. Bostwick wrote he was aware of the MMR vaccination Seth received prior to his attack of acute pancreatitis. He added, "[H] owever it is impossible to definitively relate this to his diagnosis." P. Ex. 5 at 69.

III.

EXPERT TESTIMONY

Dr. Mark Geier

Petitioner presented the testimony of Dr. Mark Geier, a practicing obstetrical geneticist.⁽⁵⁾ Dr. Geier opined, to a reasonable degree of medical certainty and assuming the accuracy of the facts as asserted by petitioner, that the most likely etiology for Seth's pancreatitis was his June 4, 1990, MMR inoculation. P. Ex. 12 at 4-5. In formulating his opinion, Dr. Geier consulted with Nelson's Textbook of Pediatrics which lists measles, mumps and rubella viruses as "known etiological agents that can cause acute pancreatitis." P. Ex. 12 at 5. Dr. Geier bases his opinion on (1) the fact that MMR vaccine contains live virus which is known to cause acute pancreatitis; (2) the temporal relationship between the vaccination and the onset of Seth's pancreatitis; and (3) the absence of an known alternative etiology.⁽⁶⁾ *Id.*; Tr. at 53.

Dr. Geier opined that the relatively short time-frame between vaccination and the onset Seth's illness (as opposed to the two week period following natural exposure to mumps virus) may be attributable to the fact that the MMR vaccine was injected and "may have gotten directly into the bloodstream."⁽⁷⁾ Tr. at 54, 78-79. Additionally, if Seth's pancreatitis was caused by an immune response, subsequent exposure to the virus such as by a booster shot, could result in an immune reaction occurring within hours. Tr. at 59. With respect to the chronicity of Seth's condition, Dr. Geier posited that whatever caused the initial acute onset of Seth's pancreatitis also caused the chronic relapses. Tr. at 63.

Dr. Joseph Bellanti

Petitioner's expert, Dr. Bellanti, is a professor of pediatrics and microbiology at Georgetown University School of Medicine.⁽⁸⁾ It is Dr. Bellanti's opinion, to a reasonable degree of medical certainty, that Seth's MMR vaccine was the cause of his pancreatitis. Tr. at 92-93.

Dr. Bellanti testified that the relatively short time period between vaccination and the onset of Seth's acute pancreatitis (as opposed to the usual interval between community contact with a wild virus and the onset of the disease) could be explained by the fact that the vaccine is delivered intramuscularly and the amount of virus being delivered is greater than that delivered by natural exposure .⁽⁹⁾ Tr. at 93-94. Dr. Bellanti based his opinion on the temporal relationship between the administration of Seth's MMR vaccination and the onset of his acute illness, the lack of any other known cause, the literature, and known principles of immunology. He summarized, "I think that this all adds up within a very great deal of medical certainty to establish a causal relationship between that vaccine and the onset of the pancreatitis."⁽¹⁰⁾ Tr. at 106.

Dr. Bellanti also explained how Seth's condition, the first manifestation of which was an acute attack, could become chronic:

The pancreas, unlike other glands, with its high content of enzymes has a propensity to becoming chronic. That is, while some acute pancreatitides can heal, if the insult is large enough you get autobreakdown of the gland itself. . . . And when it breaks down the body's inflammatory response comes in to play . . . and fibrosis begins. And if that fibrosis is severe enough it leads to abnormal healing" which produces a condition which is conducive to chronicity.

Tr. at 97.⁽¹¹⁾

Dr. Bellanti could not pinpoint the exact mechanism by which Seth's acute pancreatitis might have been caused by the MMR vaccine. Tr. at 138-39. He testified the autoimmune phenomenon occurs when the body "overshoots its ability to recognize only virus but begins destroying self." Tr. at 102. He explained further that molecular mimicry refers to when the body's immune system gets tricked by a virus that has a similar configuration to a body constituent such as the pancreas. *Id.* When asked which mechanism caused Seth's pancreatitis, Dr. Bellanti responded, "Well, one of these mechanisms I'm sure was involved in terms of either molecular mimicry or the genetic response of Seth to his own viral infection."⁽¹²⁾ Tr. at 103. Dr. Bellanti also believes that mumps virus can go directly to the pancreas itself within hours, bypassing the lymphocytes or macrophages involved in a typical immune system response. Tr. at 349-50. He is not aware of any literature supporting that view, however. Tr. at 362-63.

As to other causes of pancreatitis, Dr. Bellanti mentioned a number of different viruses, including enterovirus.⁽¹³⁾ While Seth had "a little diarrhea" after the onset of his pancreatitis, Dr. Bellanti ascribes it more to the pancreatitis itself rather than an enterovirus infection. Tr. at 115.

Dr. Bellanti believes his theory is supported by two case reports, one involving a 19-year-old woman who was inoculated with MMR and suffered the onset of acute pancreatitis 11 days later. Tr. at 118-19; P. Ex. 26 (J. Adler *et al.*, *Pancreatitis Caused by Measles, Mumps, and Rubella Vaccine*, 6 *Pancreas* 489 (1991) (hereafter, "the Adler report")). Dr. Bellanti conceded that, in this article, the authors specifically pointed to the fact that the 11 day time period between vaccination and the onset of the disease corresponded to the incubation period of the natural virus.⁽¹⁴⁾ However, he believes that does not preclude a shorter incubation period if the vaccinee was previously sensitized. Tr. at 119. In the other instance, the author of a letter to the editor of the same medical journal that published the Adler report describes a 17 year old male who developed acute pancreatitis 17 days after receipt of an MMR vaccine. R. Ex. P (L. Cebria *et al.*, *"Acute Pancreatitis Caused by Parotiditis Vaccine,"* (*Letters to the Editor*), 9 *Pancreas* 390 (1994) (hereafter "Cebria letter")).

In an attempt to ascertain whether there were any other reported instances of pancreatitis following

MMR immunization, Dr. Bellanti called the Vaccine Adverse Event Reporting System ("VAERS"). Tr. at 99. VAERS provided Dr. Bellanti with information regarding two reports of pancreatitis following the administration of vaccines. One (a four-and-a-half year old child) was reported to have developed pancreatitis 24 days following an MMR immunization. Hospital notes indicate the child was struck earlier in the day by his sister and it was unknown whether the child's pancreatitis was of traumatic or viral origin. P. Ex. 34 at 2-3. In the other case, a 15-month old child was inoculated with DPT, OPV and MMR. A narrative describing the adverse events that occurred indicate that two days following vaccination, the child developed a fever of 106° F. and exhibited jerking movements. The child was taken to an emergency room and given sponge baths until the fever subsided. Two days later, the child again spiked a fever of 106° F. and was given Tylenol and Temptra to reduce the fever. Although the narrative report does not list any abdominal complaints, the report lists pancreatitis among a long list of symptoms following immunization.⁽¹⁵⁾ P. Ex. 34 at 4. It should be noted that there is no information as to when any symptoms of pancreatitis occurred in this report and any association with the immunization is unclear. *Id.* Subsequent 60-day and one-year follow-up reports do not mention pancreatitis. R. Ex. T at 1-2.

Dr. Bellanti likened pancreatitis to diabetes which, he testified, is a "form of pancreatitis affecting the endocrine system rather than the exocrine system. . . ." Tr. at 353. Dr. Bellanti believes that an experimental model in rats shows that alpha-Interferon given to rats can cause the pancreas to be infiltrated with lymphocytes thereby causing diabetes. According to Dr. Bellanti, this shows that the pancreas can be damaged independent of any viral replication. Tr. at 352; P. Ex. 38 (D. Sobel, *et al.*, *Poly I:C Induced Development of Diabetes Mellitus in BB Rat*, 41 *Pancreas* 515 (1992)). However, Dr. Bellanti was unaware of any other published case reports or articles involving MMR vaccine and acute pancreatitis. Tr. at 120. Further, he does not know of any medical or scientific literature supporting the notion that MMR vaccine could result in chronic pancreatitis.⁽¹⁶⁾ Tr. at 140.

Dr. Sidney Berezin

Petitioner next presented the testimony of Dr. Sidney Berezin, Seth's treating pediatrician. Tr. at 144-45. Dr. Berezin believes that Seth's MMR immunization caused his pancreatitis. P. Ex. 28. He bases this opinion on the temporal relationship between the vaccination and the onset of Seth's pancreatitis, the plausibility of the notion that MMR vaccine is capable of producing pancreatitis and "ample support in the literature."⁽¹⁷⁾ *Id.* Dr. Berezin testified he had no record of Seth having experienced any prior episodes of pain similar to the pain he experienced after his MMR immunization, although his records indicated that Seth had one episode of abdominal pain with tenderness in the right lower quadrant in January 1985. Tr. at 145. Dr. Berezin disagreed with the opinion expressed by one of respondent's experts, Dr. Maksimak, that a lot of childhood abdominal pain may be undiagnosed pancreatitis. P. Ex. 27. He testified that since Seth's illness, he has screened patients with abdominal pain for increased serum amylase, and only found one case, due to an abdominal trauma. *Id.* He conceded on cross-examination, however, that he is a general pediatrician and does not have a subspecialty in gastroenterology. Tr. at 148.

Dr. Myron Shoham

Testifying next for petitioner was Dr. Myron Shoham, a gastroenterologist.⁽¹⁸⁾ Dr. Shoham believes Seth's initial episode of acute pancreatitis was causally related to his MMR vaccination. P. Ex. 29. He also believes that his subsequent episodes are "probably related to the initial episode." *Id.* Dr. Shoham relies on the temporal relationship between Seth's MMR vaccination and the onset of his pancreatitis,

the fact that he had never before experienced such an episode, the absence of another known cause, as well as the fact that "it has been well substantiated that MMR vaccination has been causally related to acute pancreatitis." ⁽¹⁹⁾ *Id.*; Tr. at 185, 187-88. Dr. Shoham also posited that after Seth's initial bout of acute pancreatitis, "in the healing process there was scarring in such a way that the pancreatic ducts and especially the secondary ducts were distorted. And the healing process was not in a normal fashion but in an abnormal fashion which then predisposes to future episodes of acute pancreatitis." Tr. at 190. Dr. Shoham referred to the findings of the ERCP which was performed in 1991 in which scarring was noted. ⁽²⁰⁾ Tr. at 213. He conceded that scarring was not found after the first episode of acute pancreatitis in June 1990, but noted that nobody looked for it at that time. *Id.*

Dr. John Bacon

Testifying first for respondent was Dr. John Bacon. ⁽²¹⁾ Dr. Bacon believes, to a reasonable degree of medical certainty, that Seth's MMR immunization was not related to the development of his acute pancreatitis. Tr. at 162. Dr. Bacon believes that the temporal relationship between Seth's MMR vaccine and the onset of his symptoms (less than 24 hours) argues strongly against, rather than supports, a causal relationship between the two events. R. Ex. N at 1. He stated, "The normal incubation period for pancreatitis is 16 to 18 days but cases may occur from 12 to 25 days after exposure." *Id.* at 1-2. Dr. Bacon acknowledged that the Adler report suggested a possible causal relationship between an MMR vaccine and the onset of symptoms 11 days later. *Id.* at 2. However, he stated that there is no evidence in any medical or scientific literature supporting such a causal relationship with onset of symptoms within 24 hours of immunization. *Id.* Further, he stated, "[t]here is no literature that is consistent with Seth Platt's claim that MMR will lead to the development of chronic pancreatitis." *Id.*

Dr. Bacon testified that the onset of symptoms within 24 hours of administration of MMR vaccine would not fit any of the known autoimmune allergic reactions. Tr. at 163-66. Seth's symptoms were not compatible with an IgE Type I mediated allergic reaction, which includes hives, wheezing, shock or anaphylaxis. Tr. at 163-64. Further, autoimmune disease Type II reactions require the production of antibodies, which would take two to three days at the least. Tr. at 164. A Type III reaction would include antigen antibody, immune complex reaction, of which serum sickness would be a classical example. Tr. at 174-75. This would involve swollen joints, fever and hives. Tr. at 175. Finally, a cell-mediated Type IV reaction (similar to that which the body produces in response to a TB skin test), takes at least two days to occur. *Id.* Based on the above, Dr. Bacon rejected the notion that Seth's initial bout of acute pancreatitis, which had its onset less than 24 hours after immunization could have been related to his MMR inoculation.

Dr. Martin Maksimak

Also testifying for respondent was Dr. Martin Maksimak, a pediatric gastroenterologist. ⁽²²⁾ Dr. Maksimak believes to a reasonable degree of medical certainty that Seth's acute pancreatitis was not caused by the MMR immunization he received on June 4, 1990. Tr. at 228. He bases his opinion on several factors. First, Dr. Maksimak believes that Seth displayed the onset of symptoms of pancreatitis prior to his June 1990 MMR vaccination. R. Ex. A at 4; Tr. at 228. He bases this on Seth's history to several doctors upon admission to the hospital of episodes of similar abdominal pain in the preceding year. R. Ex. A at 4. Dr. Maksimak testified that about 75% of pediatric patients with chronic pancreatitis suffered recurrent episodes of abdominal pain prior to their first hospital admission. ⁽²³⁾ Tr. at 231. Moreover, the brief period of time between immunization and the onset of Seth's symptoms would preclude the MMR vaccine as a causative factor. Tr. at 228. Dr. Maksimak explained the usual

incubation time for a mumps infection is approximately 14 days. He believes that the onset of Seth's symptoms only hours after his immunization renders it extremely unlikely that Seth's pancreatitis was in any way related to his immunization. R. Ex. A at 4-5. Finally, he believes the recurring nature of Seth's pancreatitis creates a medical picture that has never been documented following MMR immunization. Tr. at 228-29; R Ex. A at 3-4.

Dr. Maksimak reviewed and discussed in his report the scientific literature relating to pancreatitis following wild measles, mumps and rubella. Although pancreatitis associated with measles and rubella has been reported, it is extremely uncommon. R. Ex. A at 2. However, there are numerous case reports of pancreatitis being associated with the wild mumps virus. *Id.* The incubation period in these cases is 14-24 days but is usually in the range of 17-18 days. *Id.* at 2-3. Dr. Maksimak believes that while mumps virus is known to cause acute pancreatitis, there is no well-documented evidence that the virus has been associated with chronic recurrent pancreatitis. ⁽²⁴⁾ *Id.* at 4.

According to Dr. Maksimak, the scientific literature simply does not support the view that MMR vaccine can cause acute pancreatitis or chronic recurrent pancreatitis. ⁽²⁵⁾ R. Ex. A at 4. Dr. Maksimak cited a large study involving the administration of over six thousand doses of mumps virus vaccine to children and 163 doses to adults. Careful monitoring of side effects showed no detectable illness. *Id.*; R. Ex. J (J. Hilleman, *et al.*, *Live, Attenuated Mumps-virus Vaccine*, 278 *New England Journal of Medicine* 227 (1968)). As to the Adler report, Dr. Maksimak believes no definite association can be drawn between the patient's MMR vaccine and the onset of pancreatitis 11 days later because there had been an outbreak on the patient's college campus of live mumps virus and no serologic evidence indicated any linkage to the MMR vaccine. More importantly, she did not go on to develop chronic pancreatitis. R. Ex. A at 4; Tr. at 234. Similarly, the 17-year old boy in the Cebria letter who developed abdominal pain 17 days after receiving an MMR vaccination did not go on to develop chronic pancreatitis. Tr. at 240-41; R. Ex. P.

With respect to the ERCP studies conducted on Seth in 1991 and 1993, Dr. Maksimak testified the abnormality noted in the ducts of the pancreas could not be related to any specific episode of pancreatitis and offers no evidence of an etiology of the disease, only a "nonspecific change that occurs with chronic pancreatitis." Tr. at 236. Further, Dr. Maksimak does not believe that a severe episode of acute pancreatitis would predispose a patient to chronic pancreatitis. Tr. at 238.

Dr. Maksimak rejected Dr. Shoham's suggestion that Seth's purported keloid-forming propensity would have played any role in an increased risk of internal scarring, thereby causing recurring pancreatitis. Tr. at 250; R. Ex. U. While he acknowledged keloid formation appears to be an individual genetic condition, he explained it has only been recognized relating to abnormal scarring of skin wounds. Based on his review of medical texts, he testified there is no substantial evidence that it occurs in deeper tissues. ⁽²⁶⁾ R. Ex. U.

Dr. John Sever

Also testifying for respondent was Dr. John Sever, an expert in pediatrics, virology and immunology. ⁽²⁷⁾ Tr. at 289. Dr. Sever believes, to a reasonable degree of medical probability, that the MMR vaccine administered to Seth on June 4, 1990, did not cause his pancreatitis. Tr. at 289-90, 348. Citing the lack of any clinical, laboratory or cellular evidence that Seth had any hypersensitivity, allergy or immune reaction to the inoculation, in addition to the lack of any epidemiologic data in the literature supporting such an association, Dr. Sever rejected the notion that MMR vaccine could have caused Seth's pancreatitis. Tr. at 290. Dr. Sever testified that about eight million doses of MMR vaccine are

administered annually.⁽²⁸⁾ Tr. at 341. To Dr. Sever's knowledge, there has never been a case report of any individual experiencing a hypersensitivity response to MMR vaccine. Tr. at 336. Dr. Sever also testified that, notwithstanding the IOM Report's finding of a plausible relationship between abrupt-onset insulin dependent diabetes mellitus ("IDDM") and mumps infection, (*see* P. Ex. 42), IDDM is an entirely different disease from acute pancreatitis.⁽²⁹⁾ Tr. at 336.

As to the Adler report, Dr. Sever noted the primary association made by the author was a temporal one - that is, the patient developed pancreatitis 11 days following immunization with MMR, consistent with the incubation period of the natural disease. Likewise, the boy in the Cebria letter was noted to develop the onset of symptoms of pancreatitis 17 days after immunization with MMR -- a time frame consistent with the incubation period of the natural mumps virus.⁽³⁰⁾ R. Ex. P. Because of these two published reports, Dr. Sever would be willing to concede the possibility of a causal relationship between MMR vaccination and acute pancreatitis if the interval between inoculation and onset of symptoms coincides with the expected incubation period of the natural mumps virus. Tr. at 309-310.

IV.

DISCUSSION

Causation in Vaccine Act cases can be established in one of two ways: either through the statutorily prescribed presumption of causation, or by proving causation-in-fact. Petitioner must prove one or the other in order to recover under the Act.⁽³¹⁾ The Vaccine Injury Table lists certain injuries and conditions which, if found to occur within a prescribed time period, create a rebuttable presumption that the vaccine caused the injury or condition.⁽³²⁾ A rebuttable presumption also obtains when a petitioner proves that a Table injury has been significantly aggravated, within the Table time period, by a listed vaccine.⁽³³⁾ Petitioner may also prove that a listed vaccine caused an injury not listed on the Vaccine Injury Table.⁽³⁴⁾ Further, petitioner may prove that an underlying injury not listed on the Vaccine Injury Table was significantly aggravated by a listed vaccine.⁽³⁵⁾ In the latter two instances, there is no presumption of causation and the burden does not shift to respondent to prove a factor unrelated to the administration of the vaccine caused the injury.

Petitioner's theory of recovery is that the MMR vaccine Seth received actually caused his pancreatitis and subsequent recurrences. Pancreatitis is not a condition found on the Vaccine Injury Table. Accordingly, petitioner's claim must be analyzed under the framework of an off-Table injury. That is, no presumption of causation exists and petitioner must prove it is more likely than not that the inoculation in question in fact caused the injury alleged.

Causation-in-fact

In order to demonstrate entitlement to compensation in an off-Table case, petitioner must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused the injury alleged. §§ 11(c)(1)(C)(ii)(I) and (II); *Grant v. Secretary of HHS*, 956 F.2d 1144 (Fed. Cir. 1992); *Strother v. Secretary of HHS*, 21 Cl. Ct. 365, 369-70 (1990), *aff'd*, 950 F.2d 731 (Fed. Cir. 1991). The Federal Circuit in *Grant* summarized the legal criteria required to prove actual causation under the Vaccine Act. The court held that a petitioner must

show a medical theory causally connecting the vaccination and the injury. Causation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and

effect.

Grant, 956 F.2d at 1148 (citations omitted); *see also Strother*, 21 Cl. Ct. at 370.

Petitioner does not meet this affirmative obligation by merely showing a proximate temporal association between the vaccination and the injury. Rather, petitioner must explain *how* and *why* the injury occurred. *Strother*, 21 Cl. Ct. at 370; *see also Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1993), *cert. denied*, 469 U.S. 817 (1984) (inoculation is not the cause of every event that occurs within a ten day period following it). If petitioner places "singular reliance on the temporal relationship between the administration of the vaccine and the onset of symptoms," the claim must fail. *Thibaudeau v. Secretary of HHS*, 24 Cl. Ct. 400, 403 (1991). Nor may petitioner meet his burden by eliminating other potential causes of the injury. *Grant*, 956 F.2d at 1149. Petitioner's theory "must be supported by a sound and reliable medical or scientific explanation." *Knudson v. Secretary of HHS*, 35 F.3d 543 (Fed. Cir. 1994)

"[E]vidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation" for petitioners seeking to prove actual causation. H.R. Rep. No. 990908, 99th Cong. 2d Sess., pt. 1 at 15 (Sept. 26, 1986), *reprinted in* 1986 U.S. Code Cong. and Admin. News 8344, 8356. The general acceptance of a theory within the scientific community of a scientific theory can have a bearing on the question of assessing reliability while a theory that has attracted only minimal support may be viewed with skepticism. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786, 2797 (1993).

Under the Table injury route, after petitioner has demonstrated the requirements of Section 13(a)(1)(A), the burden shifts to the respondent to prove the injury was caused by factors unrelated to the vaccination in question pursuant to section 13(a)(1)(B). *Matthews v. Secretary of HHS*, 18 Cl. Ct. 514, 518 (1989); *O'Connor v. Secretary of HHS*, 24 Cl. Ct. 428, 429-30 n. 2 (1991), *aff'd*, 975 F.2d 868. In an actual causation case such as this, however, the inquiry is "collapsed into a single determination: On the record as a whole, has petitioner proven, by a preponderance of the evidence, that her injury was in fact caused by the administration of a listed vaccine, rather than by some other superseding intervening cause?" *Johnson v. Secretary of HHS*, 33 Fed. Cl. 712, 722 (1995); *aff'd* 99 F.3d 1160 (Fed. Cir. 1996). *See also, Bradley v. Secretary of HHS*, 991 F.2d 1570, 1575 (Fed. Cir. 1993); *Munn v. Secretary of HHS*, 970 F.2d 863, 865 (Fed. Cir. 1992); *Wagner v. Secretary of HHS*, No. 90-2208V, 1997 WL 617035 (Fed. Cl. Spec. Mstr. Sept. 22, 1997) (dec. on remand). *But see Wagner v. Secretary of HHS*, 37 Fed. Cl. 134, 138 (1997) (once petitioner puts on her prima facie case, the burden shifts to respondent to prove a factor unrelated to the administration of the vaccine caused the injury); *O'Connor v. Secretary of HHS*, 24 Cl. Ct. 428, 429-30 n.2 (1991), *aff'd*, 975 F.2d 868 (Fed. Cir. 1992); *McClendon v. Secretary of HHS*, 24 Cl. Ct. 329, 333 (1991), *aff'd*, 41 F.3d 1621 (1994).

In order to answer the single inquiry of whether, based on the record as a whole, the evidence preponderates in favor of a finding that Seth's pancreatitis was caused by the vaccination in question, one must pursue a two-step analysis: (1) *can* MMR vaccine cause pancreatitis? and (2) *did* the MMR inoculation in question in-fact cause Seth's pancreatitis *in this case*? *See Guy v. Secretary of HHS*, No. 92-779V, 1995 WL 103348 (Fed. Cl. Spec. Mstr. Feb. 21, 1995) (two-step causation-in-fact analysis used); *Alberding v. Secretary of HHS*, No. 90-3177V, 1994 WL 110736 (Fed. Cl. Spec. Mstr. March 18, 1994) (two-step causation-in-fact analysis used); *Housand v. Secretary of HHS*, No. 94-441V, 1996 WL 282882 at *5 (Fed. Cl. Spec. Mstr. May 13, 1996) (two-step cause-in-fact analysis used).

1) *Can an MMR vaccination in fact cause pancreatitis?*

As noted above, a temporal relationship alone does not suffice to prove causation in an off-Table case. Although the Federal Rules of Evidence do not apply in Program proceedings, the United States Court

of Federal Claims has held that "*Daubert* is useful in providing a framework for evaluating the reliability of scientific evidence. *Terran v. Secretary of HHS*, 41 Fed. Cl. 330, 336 (1998) (citing *Leary v. Secretary of HHS*, No. 90-1456V, 1994 WL 43395, at *9 (Fed.Cl.Spec.Mstr. Jan. 31, 1994)). In *Daubert*, the Supreme Court noted that scientific knowledge "connotes more than subjective belief or unsupported speculation." *Daubert*, 11 S.Ct. at 1795. Rather, some application of the scientific method must have been employed to validate the expert's opinion. *Id.* Factors relevant to that determination may include:

whether the theory or technique employed by the expert is generally accepted in the scientific community; whether it's been subjected to peer review and publication; whether it can be and has been tested; and whether the known potential rate of error is acceptable.

Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1316 (9th Cir. 1995)(Kozinski, J.), *on remand from* 113 S.Ct. 2786 (1993).

When viewed in light of the factors listed above, the undersigned concludes that it is reasonable to find plausible the theory that MMR vaccine can cause acute pancreatitis. I base this conclusion largely on the fact that not only petitioner's experts, but two of respondent's experts, Dr. Bacon and Dr. Sever, acknowledged the possibility, based on the Adler report and the Cebria letter, that MMR vaccine could trigger the onset of acute pancreatitis if the onset is within the incubation period of the natural mumps virus. Dr. Bacon and Dr. Sever were both highly credible witnesses. Their willingness to concede the plausibility of causation where the incubation period matches that of the natural mumps virus suggests some degree of acceptance of that premise in the scientific community. That, in conjunction with the Adler report and Cebria letter, both published in a respectable medical journal, convinces me of the possibility that MMR vaccine may cause acute pancreatitis.

2) *Did the MMR vaccination administered to Seth Platt cause his acute pancreatitis and subsequent recurring attacks?*

With respect to this second question, petitioner's case is not nearly as convincing. As an initial matter, I should note that I found respondent's experts, Dr. Bacon, Dr. Maksimak and Dr. Sever, to be more convincing in their testimony than petitioner's experts. Dr. Bellanti, while certainly highly credentialed and knowledgeable, offered what I believe to be only unproven theories that do not enjoy general acceptance in the medical community on the issue of the abrupt onset of Seth's symptoms following his immunization. Nor was I satisfied with petitioner's experts' theories of the chronicity of Seth's condition. Finally, I find it likely that Seth's pancreatitis had an insidious onset that predated his initial hospitalization. Accordingly, based on all the evidence in the record, I find that there is not a preponderance of the evidence that Seth's pancreatitis was caused by his MMR vaccine administered less than 24 hours prior to the onset of his symptoms. My conclusion is explained more fully below.

While I have found it plausible that MMR vaccine might cause acute pancreatitis, there are only two published anecdotal reports suggesting such a link. In both cases, the onset of pancreatitis was well within the time period that might be expected for the incubation period of the mumps virus. Neither of the VAERS reports provides convincing support either. In one, the child's symptoms of pancreatitis began 24 days following immunization, within the incubation period expected for the mumps virus. Further, the child had been struck by his sibling earlier in the day and trauma was not ruled out as the cause for the episode. The child apparently recovered fully. In the second report, there is no clear evidence that the child even suffered pancreatitis following immunization.

Dr. Bellanti advanced a number of scenarios explaining a potential mechanism that would bring about

an abrupt onset of pancreatitis following MMR immunization, based on principles of immunology. These theories include a genetically based response, an autoimmune phenomenon and molecular mimicry. According to Dr. Bellanti, every time a vaccine booster is administered, the body mounts a greater immunologic response and the response time will be significantly shortened. *Id.* He testified a booster vaccine will produce a response in 2 to 3 days or less, whereas the initial vaccination might have an incubation period of 7 to 10 days. Tr. at 104. He also alluded to the fact that the portal of entry and the amount of virus being injected may affect the response time. Tr. at 93-94. I was simply not convinced by Dr. Bellanti's theories regarding how an immunologic response could cause such an abrupt onset of pancreatitis as Seth experienced. It is not evident that such theories are generally accepted in the medical or scientific community. Dr. Bellanti could not point to a single case report of such a sudden onset following MMR immunization in all of medical history.

Moreover, Dr. Bellanti's theory that pancreatitis is analogous to IDDM is also unavailing. IDDM is a genetically determined disease affecting different cells and functions of the pancreas than pancreatitis. There is no evidence that Seth suffers from IDDM. The IOM concluded the evidence was inadequate to accept or reject a causal relationship between mumps vaccine and IDDM, further attenuating Dr. Bellanti's hypothesis.

While Dr. Bellanti testified at length about the various theories mentioned above, he did not provide any medical or scientific evidence that logically link these theories to the facts in this case. As respondent's expert, Dr. Sever, testified persuasively, "There is no evidence in the medical literature that mumps vaccine induces molecular mimicry in pancreatic or other tissues. There is no evidence of unusual genetic susceptibility or responses to mumps vaccine which cause chronic pancreatitis. There is no evidence that mumps vaccine produces anamnestic responses which would cause tissue damage." R. Ex. Q at 2. He further explained that, following a second dose of mumps vaccine, there is no known autoimmune response involving the pancreas. Tr. at 306.

Moreover, none of petitioner's experts were at all convincing in explaining the recurring nature of Seth's condition. There is no evidence in the medical literature to support the notion that an MMR vaccine can cause chronic pancreatitis. None of the case reports or letters submitted supports any causal connection between MMR vaccination and a chronic or relapsing course of pancreatitis. There is not even convincing medical literature to support the notion that wild mumps virus can cause relapsing pancreatitis. The Wood case report described recurrent pancreatitis following natural mumps infection. However, an anatomical anomaly was discovered which, according to petitioner's Dr. Maksimak, could account for the chronicity of the disease. R. Ex. A. In the Graham letter, the patient suffered an initial bout of pancreatitis following a mumps infection and was asymptomatic for 24 years. Dr. Maksimak dismissed the relationship between the episodes as too temporally attenuated. *Id.*

Even if Dr. Bellanti's theories are accurate, however, I find it likely that Seth's pancreatitis actually predated his MMR immunization. Although at the hearing in this matter, Seth denied having had prior abdominal pain of the nature he experienced following his June 4, 1990, MMR vaccination, statements he made to various different medical professionals during his first hospitalization contradict his testimony. Upon admission to the hospital, Seth admitted to "similar" abdominal pain on a number of occasions in the preceding year. Dr. Maksimak testified that the majority of patients with chronic pancreatitis present with a history exactly like Seth's, as recorded contemporaneously in hospital records. As the Federal Circuit noted in *Cucuras v. Secretary of HHS*, "oral testimony in conflict with contemporaneous documentary evidence deserves little weight." 993 F.2d 1525, 1528 (Fed. Cir. 1993) citing *United States v. United States Gypsum Co.*, 333 U.S. 364 (1947). The Federal Circuit further stated:

Medical records, in general, warrant consideration as trustworthy evidence. The records contain

information supplied to or by health professionals to facilitate diagnosis and treatment conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Cucuras at 1528.

In determining how to weigh oral testimony against conflicting medical record evidence, the United States Court of Federal Claims has stated that "written documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later." *Reusser v. Secretary of HHS*, 28 Fed. Cl. 516, 523 (1993) (quoting *Murphy v. Secretary of HHS*, 23 Cl.Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. denied*, 113 S.Ct. 463 (1992)). I find it likely, as Dr. Maksimak has opined, that Seth's pancreatitis predated his June 4, 1990, MMR vaccination. While Seth now disputes that the pain in prior episodes of abdominal pain was similar to the pain he experienced on June 5, 1990, and while he may now be convinced of that fact, he told a number of care providers something different. His contemporaneous statements to a number of different health care professionals during his initial hospitalization convince me Seth experienced prior similar abdominal pain, albeit perhaps not as intense as the pain that resulted in his first hospitalization. Dr. Maksimak was highly convincing in his testimony that Seth's course fit the profile of the vast majority of pediatric patients who suffer chronic relapsing pancreatitis. In sum, I find it more likely than not that Seth's pancreatitis began before his June 4, 1990, MMR immunization. Petitioner has advanced no theory that the immunization significantly aggravated an underlying condition.

In short, petitioner's underlying hypothesis is just that -- purely theoretical. Even though I have found that MMR could plausibly cause pancreatitis, petitioner has failed to prove, *in this particular case*, that the immunization was more likely to have caused his pancreatitis. After carefully reviewing and considering all of the contemporaneous medical records and the testimony presented, I find that petitioner has not met his burden of demonstrating, by a preponderance of the evidence, that Seth's pancreatitis was caused by his MMR immunization.

V.

FINDINGS OF FACT

1. As a competent adult, petitioner has the requisite capacity to bring this action. Section 11(b)(1)(A).
2. Petitioner has not previously collected an award or settlement of a civil action in connection with any alleged injury sustained by Seth due to the administration of the MMR vaccine in question. Section 11(c)(1)(E); Petition at 2.
3. Seth was administered a vaccine listed in the Vaccine Injury Table. Section 11(c)(1)(B)(I)(I); Petition at 1.
4. Said vaccine was administered in the United States, in Spring Valley, New York. Section 11(c)(1)(B)(I)(I); Pet. at 1.
5. There is not a preponderance of the evidence that Seth's pancreatitis was caused by the MMR vaccination he received on June 4, 1990.
6. There is not a preponderance of the evidence that petitioner expended in excess of \$1000 in unreimbursed medical expenses as the result of a vaccine-related injury. [\(36\)](#)

VI.

CONCLUSION

Based on the foregoing, the undersigned finds, after considering the entire record in this case, that petitioner is not entitled to compensation under the Vaccine Act. In the absence of a motion for review filed pursuant to RCFC Appendix J, the clerk of the court is directed to enter judgement in accordance herewith.

IT IS SO ORDERED.

Elizabeth E. Wright

Special Master

1. The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C.A. §§ 300aa-1 through -34 (West 1991 & Supp. 1998)). References shall be to the relevant subsection of 42 U.S.C.A. § 300aa.
2. The evidence in the record consists primarily of exhibits submitted as part of the petition filed in this case ("P. Ex. ____"), respondent's exhibits filed in this matter ("R. Ex. ____"), plus evidence taken at the evidentiary hearing in this matter ("Tr. at ____").
3. Later, Seth testified that, at the time he told physicians during his first hospitalization about prior abdominal pain, he was actually referring to a stomach flu or virus, but that the doctors had failed to record that. Tr. at 278.
4. Seth also testified he had stomach pain in 1985 that was initially thought, erroneously, to be appendicitis. Tr. at 11.
5. Dr. Geier is board certified in obstetrical genetics and holds a Ph.D. in genetics. P. Ex. 12. He is licensed to practice in Maryland and Virginia. *Id.* While working at the National Institutes of Health, Dr. Geier performed research involving the injection of viruses into mice and the rates at which such viruses reached the organs of the mice. Tr. at 51, 54.
6. Dr. Geier cautions, however, that "it is not possible to absolutely rule-out some of the other etiologies of Seth's acute pancreatitis." P. Ex. 12 at 5.
7. While the MMR vaccine is administered intra-muscularly, Dr. Geier testified, there is a chance it got directly into the bloodstream if the needle inadvertently hit a small blood vessel. Tr. at 55, 69.
8. Dr. Bellanti also directs the International Center for Interdisciplinary Studies of Immunology, the

Division of Virus Disease and Immunology in the Department of Laboratory Medicine, and the Division of Allergy and Immunology in the Department of Pediatrics. P. Ex. 33; Tr. at 82-83. He has published numerous articles related to immunology, some dealing specifically with the immunologic response to either natural infection or viral vaccines. Tr. at 83. He is board certified in the fields of pediatrics and allergy and immunology. P. Ex. 33.

9. While he found Dr. Geier's theory about the vaccine inadvertently hitting a blood vessel upon being administered "attractive," Dr. Bellanti did not necessarily subscribe to it. Rather, he believed that prior sensitization to the virus could lead to a rapid immune response. Tr. at 113-14.

10. Based on conversations with Seth, Dr. Bellanti determined that Seth did not have pancreatitis prior to the administration of the MMR vaccine, because the pain Seth described to him as having occurred after the vaccination was different from pain he had experienced previously. Tr. at 107-09. He conceded, however, that pancreatitis can have an insidious onset. Tr. at 109.

11. Later, Dr. Bellanti testified, "[T]he pancreas is a setup for chronicity due to the breakdown . . . of enzymes which continually autodigest and an ongoing attack *I think makes it quite plausible*." Tr. at 106 (emphasis added). He opined that a damaged pancreas could be vulnerable to a variety of insults. Tr. at 107.

12. Later, Dr. Bellanti testified, "[W]e could invoke many theories. We can invoke molecular mimicry. We could invoke the genetics. We can invoke the anamnestic response. And all of that is really theoretical. The fact of the matter . . . is that it does happen in two days." Tr. at 129.

13. Enterovirus is one of a subgroup of viruses that infect the gastrointestinal tract, including poliovirus, coxsackieviruses and echoviruses. Dorland's Illustrated Medical Dictionary 561 (27th ed. 1988) (hereafter, "Dorland's").

14. Dr. Bellanti also conceded that in the Adler report, the woman was inoculated because there was an outbreak of wild measles on campus. Measles is known to cause pancreatitis. Tr. at 122.

15. Dr. Bellanti did not have any information that either of the cases resulted in chronic pancreatitis. Tr. at 100. Further, he conceded that in all likelihood, the 15-month-old had never before been inoculated with MMR vaccine. Tr. at 126. However, he speculated she may have been exposed to wild mumps virus, thereby sensitizing her to the vaccination. *Id.*; Tr. at 129.

16. Dr. Bellanti conceded that in large scale trials of attenuated mumps vaccine, the authors specifically looked for increases in serum amylase (indicating pancreatitis) but it did not appear. Tr. at 132.

17. When asked which articles he relied on, Dr. Berezin mentioned the Adler report but could not specifically cite any other articles. Tr. at 155-56.

18. Dr. Shoham is in private practice in gastroenterology and is director of the gastroenterology lab at Fair Oaks Hospital in Fairfax, Virginia. He is board certified in internal medicine and gastroenterology. P. Ex. 32.

19. Dr. Shoham clarified in his testimony that he was aware of two case reports, one of which he read (the Adler report), which indicates pancreatitis as a complication of vaccination. Tr. at 187-88. He did not read the other report. Tr. at 200. As to the Adler report, Dr. Shoham conceded that the authors relied in part on the fact that the woman developed pancreatitis 11 days following immunization with MMR,

which would coincide with the incubation period of the naturally occurring disease. He also acknowledged that the woman's second bout of pancreatitis was attributed to mononucleosis. Tr. at 205-06.

20. In his initial report in this case, Dr. Shoham stated he agreed with respondent's expert, Dr. Maksimak, that the single lesion in Seth's pancreatic duct may have been related to some other cause. P. Ex. 29 at 1.

21. Dr. Bacon is board certified in pediatrics and in allergy and immunology. He is an associate professor of pediatrics at the University of Maryland Hospital and has a private practice in allergy. R. Ex. O.

22. Dr. Maksimak is currently a clinical assistant professor in the Department of Pediatrics at Jefferson Medical College and the Director of the Department of Pediatric Gastroenterology and Nutrition at the Geisinger Clinic. He is board certified in pediatrics and pediatric gastroenterology. R. Ex. B. Dr. Maksimak has had much experience caring for pediatric patients with chronic pancreatitis. R. Ex. A at 1. He is credited with a number of publications in his field. R. Ex. B.

23. In cases of acute pancreatitis that do not become chronic or relapsing, "probably zero" percent of patients have a prior history of similar abdominal pain, according to Dr. Maksimak. Tr. at 252. In addition, it would be unusual for multiple episodes of abdominal pain to persist three to four days, as the typical "common bellyache" one would see in a child or teenager would last only a day or so. Tr. at 232.

24. Dr. Maksimak noted two cases in which abdominal pain was reported to have recurred following mumps virus. In one case, a 4½ year old boy developed mumps with symptoms including abdominal and testicular pain. Within a few months, the child began to experience recurring episodes of abdominal pain in the years after his infection. Tr. at 242-244; R. Ex. A at 3; R. Ex. H (C. B. Wood *et al.*, *Chronic Pancreatitis in Childhood Associated with Mumps Virus Infection*, 28 British Journal of Clinical Practice 67 (1974) (hereafter "the Wood report")). At age 15, he was diagnosed as having pancreatitis. After having an ERCP, the patient was found to have an anatomical anomaly which, in Dr. Maksimak's view, was the probable cause for his recurring pancreatitis. R. Ex. A at 3. A letter to a medical journal in 1980 outlined the history of a man who had experienced a mumps infection at age 34, along with symptoms including severe abdominal pain lasting for about one week. At age 58, he began to suffer episodes of severe epigastric pain and he was diagnosed with pancreatitis at age 60. Tr. at 245-46; R. Ex. A at 3; R. Ex. I (J. Graham, *Mumps Causing Chronic Calcific Pancreatitis*, 2 Medical Journal of Australia 454 (1980) (hereafter "the Graham letter")). Dr. Maksimak believes the letter provides no evidence of linkage between the initial mumps infection and the patient's pancreatitis diagnosed at age 60. R. Ex. A at 3-4.

25. Dr. Maksimak testified that the cause of pediatric pancreatitis remains idiopathic in about half of the cases. Tr. at 230. Further, when a particular cause has been identifiable, in Dr. Maksimak's experience, recovery has been complete with no recurrences. *Id.*

26. Dr. Maksimak referred to a portion of a medical textbook, which describes a keloid formation as involving a situation in which "an abnormal amount of collagen is formed in the connective tissues, producing a large bulging tumorous scar." R. Ex. U at unnumbered p. 3. The textbook goes on to state that keloids have "only been recognized in skin wounds but the same excessive scarring may occur in deeper tissues as well, *although we do not have substantial evidence that it does.*" *Id.* (emphasis added).

27. Dr. Sever is a professor of pediatrics, obstetrics and gynecology and microbiology and immunology

at George Washington University School of Medicine. He holds a Ph.D. degree in microbiology in addition to his medical degree. Tr. at 287; R. Ex. R. Dr. Sever is board certified in pediatrics. He is credited with numerous publications. His primary research has been in the area of infectious diseases. Tr. at 287. Dr. Sever has studied and published articles on a number of viral vaccines, including measles, rubella and mumps. Tr. at 287-89.

28. Around four million of those are second doses of MMR vaccine. Tr. at 335-36

29. It should be noted that although the IOM found biologic plausibility in the notion that natural mumps virus infection could trigger IDDM in some individuals, the IOM concluded the evidence was "inadequate to accept or reject a causal relationship between measles or mumps vaccine and IDDM." P. Ex. 42 at 159.

30. The natural mumps virus has an incubation period of between 11 and 18 days, according to Dr. Sever. Tr. at 291.

31. Petitioner must prove his case by a preponderance of the evidence, which requires that the trier of fact "believe that the existence of a fact is more probable than its nonexistence before [the special master] may find in favor of the party who has the burden to persuade the [special master] of the fact's existence." *In re Winship*, 397 U.S. 358, 372-73 (1970) (Harlan, J., concurring) *quoting* F. James, Civil Procedure 250-51 (1965). Mere conjecture or speculation will not establish a probability. *Snowbank Enter. v. United States*, 6 Cl.Ct.. 476, 486 (Cl. Ct. 1984).

32. Section 14(a).

33. Section 11(c)(1)(C)(i).

34. Section 11(c)(1)(C)(ii).

35. *Id.*

36. This is because I cannot conclude that any expenses incurred on Seth's behalf were vaccine-related.